OCT 17 2011 K112439

FUJIFILM

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510(k) Summary

Applicant/Submitter Information:	FUJIFILM Medical Systems U.S.A., Inc. 419 West Avenue Stamford, Connecticut 06902 Telephone: (301) 251-1092 Facsimile: (203) 602-3785
Contact:	Jyh-Shyan Lin Senior Manager of Regulatory, Quality and Clinical Affairs
Date Prepared:	August 22, 2011
Trade/Proprietary Name:	FUJIFILM Synapse Workstation Software Version 3.3.0
Common/Usual Name:	Medical Image Processing Workstation
Classification Name:	Picture Archiving and Communications Systems (PACS)
Establishment No.:	2443168
Panel:	Radiology
Device Classification:	Class II
Product Code:	LLZ
Regulation Number:	21CFR 892.2050
Predicate Device(s):	Fuji Synapse Workstation Software Version 3.1.0 (K051553) Fuji's Computed Radiography Mammography Suite (FCRMS) software (P050014)

Description of Device:

The FUJIFILM Synapse Workstation Software Version 3.3.0 is PACS workstation software and an integral component of the Fuji Synapse PACS. Synapse Workstation Software Version 3.3.0, provides processing, viewing and manipulation of radiological data including images, reports, patient status, and clinical information. The workstation utilizes a folder structure providing easy navigation and organization of images, studies, documents, etc. that most users are familiar with from Microsoft Explorer and other Windows applications. The workstation contains workflow scripting and hanging protocols designed to maximize productivity and allow each user to tailor the workstation operation to their individual requirements. The common and basic image manipulation functions such as window/level and window/width variation, magnification, density value, etc., are available for mammography as well as non-mammography images. In addition to common image manipulation functions the Synapse Workstation Software Version 3.3.0 provides image processing sub-systems for processing images from various modality types such as Fuji CR, Fuji MG, CT, along with general image processing for any SOP class image.

Substantial Equivalence:

The FUJIFILM Synapse Workstation Software Version 3.3.0 is substantially equivalent to the predicate devices, Synapse Workstation Software Version 3.1.0 and the MgforProcessing IPSS is the same as that provided by Fuji's Computed Radiography Mammography Suite (FCRMS) software (P050014). The major change is that Version 3.3.0 will now be capable of processing MG images and the indications for use statement has changed slightly from the Synapse Workstation Software Version 3.1.0 IFU to address the fact that Version 3.3.0 will now be able to process DICOM MG images, functionality that was approved in PMA P50014, with the contingency that it may be added to a Fuji review workstation.

Indications for Use:

FUJIFILM Synapse Workstation Software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with Fuji Synapse PACS. The FUJIFILM Synapse Workstation is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The Synapse Workstation can process medical images from the following modality types: plane X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine, and images from other DICOM compliant modalities.

The Synapse Workstation may be used to process DICOM MG "For Processing" images and also for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible displays for mammography.

Safety Information:

The FUJIFILM Synapse Workstation Software Version 3.3.0 introduces no new safety or efficacy issues other than those already identified with the predicate devices. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate level of concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Conclusion:

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Jyh-Shyan Lin, Ph.D.
Senior Manager, Regulatory, Quality, and Clinical Affairs
FUJIFILM Medical Systems, U.S.A, Inc.
419 West Avenue
STAMPFORD CT 06902

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Re: K112439
Trade/Device Name: SYNAPSE Picture Archiving and Communications Systems (PACS) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 22, 2011
Received: August 24, 2011

Dear Dr. Lin:

This letter corrects our substantially equivalent letter of October 17, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K112439

Device Name: FUJIFILM Synapse Workstation Software Version 3.3.0

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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